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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/712,654	11/12/2003	Sylvia A. Norman	GP141-03.UT	8961
21365	7590	06/07/2006	EXAMINER	
GEN PROBE INCORPORATED 10210 GENETIC CENTER DRIVE SAN DIEGO, CA 92121			BASKAR, PADMAVATHI	
			ART UNIT	PAPER NUMBER
			1645	

DATE MAILED: 06/07/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Applicati n N .</b>	<b>Applicant(s)</b>	
	10/712,654	NORMAN ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Padmavathi v. Baskar	1645	

**-- The MAILING DATE f this communicati n appears n the cover sheet with the c rresp ndence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 13 March 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-33 is/are pending in the application.
- 4a) Of the above claim(s) 7-13,15,16,18 and 31 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-6,14,17,32 and 33 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)               | Paper No(s)/Mail Date. _____  |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>11/03, 4/04, 8/04, 1/05, 8/05, 10/05</u>                                  | 6) <input type="checkbox"/> Other: _____                                    |

## **DETAILED ACTION**

### ***Amendment***

1. Applicant's response to restriction filed on 3/13/06 is acknowledged.

### ***Election***

2. Applicant's election Group II claims 1-6,14,17, and 32-33 drawn to oligonucleotide hybridizes specifically to the pagA target sequence and a kit comprising said oligonucleotide with traverse is acknowledged.

The traversal on the ground(s) that the Examiner must examine the claims on the merits even though they are directed to independent and distinct inventions. See, the MPEP at 803.01. and the search and examination of the entire application would not be an undue burden.

This is not found persuasive because the inventions products are deemed to be patentably distinct as stated in the previous office action. In regard to burden of search and examination, MPEP 803 states that a burden can be shown if the examiner shows either separate classification, different field of search or separate status in the art. In the instant case a burden has been established in showing that the inventions of the Groups are classified separately necessitating different searches of issued U.S. Patents. However, classification of subject matter is merely one indication of the burdensome nature of search. The literature search, particularly relevant in this art, is not co-extensive, because, for example, search and examination issues for nucleic acid vaccines are different and would not encompass protein vaccines. Additionally, it is submitted that the inventions of the separate Groups have acquired a separate status in the art. Clearly different searches and issues are involved in the examination of each Group.

### ***Status of claims***

3. Claims 1-33 are pending.

Art Unit: 1645

Claims 1-6,14,17, and 32-33 drawn to oligonucleotide hybridize specifically to the pagA target sequence and a kit is under examination as an elected invention. Applicant is advised to amend the claims to the elected invention, pagA target sequence.

Claims 7-13, 15-16, 18 and 31 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected group.

***Priority***

4. Applicant's claim for domestic priority to the provisional applications 60/426,552 11/15/2002 and claims benefit of 60/471,082 05/16/2003 under 35 U.S.C. 119(e) is acknowledged.

***Information Disclosure Statement***

5. Information Disclosure Statements filed on 11/03,4/04,8/04, 1/05, 8/05,10/05, are acknowledged and a signed copy of each is attached to this Office action.

***Claim Rejections - 35 USC 101***

6. 35 U.S.C. 101 reads as Follows

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title.

7. Claims 1-6 and 14 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The product, oligonucleotide as claimed, has the same characteristics as that found in nature. To overcome this rejection the Examiner suggests the amendment of the claims to include purity limitations, which would distinguish the characteristics of applicant's product from the product, as it exists in nature. It is further suggested that such limitation include the terminology "purified and isolated" (i.e. if such purity is supported in the specification) and/or a description of what applicant's protein is "free of" relative to the natural source. ( see Farbenfabriken of Elberfeld Co. v. Kuehmsted, 171 Fed. 887, 890 (N.D. Ill. 1909)

Art Unit: 1645

(text of claim at 889); Parke-Davis & Co. v. H.D. Mulford Co., 189 Fed. 95, 103, 106, 965

(S.D.N.Y. 1911) (claim 1); and In re Bergstrom, 427 F.2d 1394, 1398, 1401-1402 (CCPA 1970).

***Claim Rejections - 35 USC 112, second paragraph***

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 1-6, 14, 17, 32 and 33 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-6 are rejected for the recitation of "contains" and "consists of" in the same claim and is not clear what are the metes and bound of these terms as claimed.

Claims 2-6, 14 and 17 are indefinite over the recitations of "an oligonucleotide" because this phrase lacks proper antecedent basis as claims do not refer to "the " since claims depend from claim 1 which refers to " an".

Claims 3-6 are rejected as being vague as it is not clear which oligonucleotide consist SEQ.ID.NO: 1 or 2 or 3 etc since more than one oligonucleotide is recited in the claims.

Claims 32 and 33 are confusing as it is not clear what is being claimed because whether applicant is claiming a kit for detecting *B.anthraxis* using pagA target sequence or capB sequence. Accordingly, it is not clear as to whether the claims are intended to be limited to multiple oligonucleotides or to a single oligonucleotide.

Claim 32 is objected as it depends from a non-elected method claim.

***Claim Rejections - 35 USC § 102***

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

Art Unit: 1645

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

11. Claims 1-6 and 14 are rejected under 35 U.S.C. 102(e) as being anticipated by Lee et al (U.S. Patent No. 6,770,479).

Lee et al disclose an isolated nucleotide sequence SEQ.ID.NO: 4 (see, the sequence alignments) *B. anthracis* which is 100% identical to the claimed SEQ.ID.NO: 21, 22, 23 and 24 and therefore they hybridize to the claimed oligonucleotide. The claims as written do not require isolated oligonucleotide consisting of a particular sequence. But, rather the claims include nucleotides containing oligomer of SEQ ID NO: 21 22, 23 and 24 that are present in the disclosed sequence. Lee et al's nucleotide has each of the same structural features as the claimed oligonucleotides of SEQ.ID.NO: 21, 22, 23 and 24. Accordingly, the prior art sequence specifically binds to pagA target sequence of *B. anthracis*. It is noted that the claims do not require any particular conditions of hybridization. Under suitable hybridization conditions, the nucleotide sequence of Lee would be expected to specifically hybridize to *B. anthracis* DNA, and contains a sequence SEQ.ID.NO: 1 or 2 or 3 or 4 or 5 or 6. Since the sequence include oligonucleotides that are 100% complementary to *B. anthracis*, it reads on claim 14 oligonucleotide DNA or mixed DNA etc. The prior art anticipated the claimed invention.

**Remarks**

12. No claims are allowed.

**Conclusion**

13. Papers related to this application may be submitted to Group 1600, AU 1645 by facsimile transmission. Papers should be transmitted via the PTO Fax Center, which receives transmissions 24 hours a day and 7 days a week. The transmission of such papers by facsimile must conform to the notice published in the Official Gazette, 1096 OG 30, November 15, 1989. The Right Fax number is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PMR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PMR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PMR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Padma Baskar Ph.D., whose telephone number is ((571) 272-0853. A message may be left on the Examiner's voice mail system. The Examiner can normally be reached on Monday to Friday from 6.30 a.m. to 4.00 p.m. except First Friday of each bi-week.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (571) 272-0864. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.



Padma Baskar Ph.D.



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